

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 1995F-0221]

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Certifier

D. Hawkins

Food Additives Permitted in Feed and Drinking Water of Animals; Natamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of natamycin in broiler chicken feeds. Natamycin will be added to broiler chicken feed at a level of 11 parts per million (ppm) to retard the growth of *Aspergillus parasiticus* in the feed for up to 14 days after the addition of natamycin. This action is in response to a food additive petition filed by Arkion Life Sciences of Wilmington, DE.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and requests for a hearing by [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit written objections and requests for a hearing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic objections to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Karen Ekelman, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6653, e-mail: kekelman@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In a notice published in the **Federal Register** of September 20, 1995 (60 FR 48715), FDA announced that a food additive petition (animal use) (FAP 2234) had been filed by DuCoa L.P., P. O. Box 219, Highland, IL 62249–1105. The petition proposed that part 573—*Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) be amended to provide for the safe use of natamycin in broiler chicken feeds, at the rate of 11 ppm, for retarding growth of *A. parasiticus*, *Penicillium rubrum*, and *Fusarium moniliforme*. The notice of filing of FAP 2234 provided for a 60-day comment period. No comments have been received.

On June 6, 1996, the Center for Veterinary Medicine (CVM) denied the petition because data submitted in support of some sections (utility, proposed purposes and amounts, proposed regulation, and proposed label) of the petition were determined to be inadequate. At that time, CVM informed DuCoa L.P., that the company could either amend the petition by submitting additional data to address concerns expressed in the letter, or withdraw the petition as provided for in § 571.7 (21 CFR 571.7).

On July 31, 2001, the sponsor amended the petition to seek approval for the use of natamycin in broiler chicken feeds, at a level of 11 ppm to retard the growth of *A. parasiticus* in the feeds for up to 14 days.

In a letter that CVM received from the petitioner on March 20, 2003, the petitioner informed FDA that sponsorship of natamycin for the intended use had been transferred from DuCoa L.P., Highlands, IL, to Arkion Life Sciences, 3521 Silverside Rd., Wilmington, DE 19810. The transfer of sponsorship was announced in the **Federal Register** of May 22, 2003 (68 FR 28010). Data

submitted by the sponsor in support of the petition permit an independent evaluation of the ability of natamycin to achieve the intended purpose in a safe manner. The sponsor submitted data that show that this level of natamycin will not present a human food safety concern. The petition also includes satisfactory information about the chemical identity of natamycin and indicates that natamycin will achieve its intended effect in a manner that is safe to broiler chickens consuming the treated feed.

II. Conclusion

FDA concludes that the data establish the safety and utility of natamycin (CAS No. 7681–93–8) for use as proposed and that the regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at CVM (see **ADDRESSES**) by appointment with the information contact person (see **INFORMATION CONTACT**). As provided in § 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic

objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR part 573

Animal feeds, Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Section 573.685 is added to read as follows:

§ 573.685 Natamycin.

The food additive natamycin (CAS No. 7681-93-8) may be safely used in broiler chicken feeds in accordance with the following specifications:

(a) The additive is a stereoisomer of 22-[(3-amino-3,6,dideoxy-B-D-mannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.0⁵, 7] octacos-8,14,16,18,20-pentaene-25-carboxylic acid with the empirical formula C₃₃H₄₇NO₁₃.

(b) The additive shall conform to U.S.P. specifications.

(c) The additive (as part of a premix composed of calcium carbonate, natamycin, and lactose) is used for retarding the growth of *Aspergillus parasiticus* in broiler chicken feeds for up to 14 days after the addition of natamycin.

(d) Each pound (454 grams (g)) of the premix shall contain 434 (g) of calcium carbonate, 10 g of natamycin activity, and 10 g of lactose. The premix shall be mixed into broiler chicken feed at the rate of 1 pound (0.454 kilograms (kg)) per ton (908 kg) of feed to provide natamycin at a level of 11 parts per million (ppm). The premix shall be thoroughly mixed into the dry components of the broiler chicken feed before adding the liquid components. Broiler feeds to which the natamycin premix is added shall be used within 4 weeks of addition of the premix.

(e) To assure the safe use of the additive, the label or labeling of the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The name and CAS number of the additive, and its purpose.

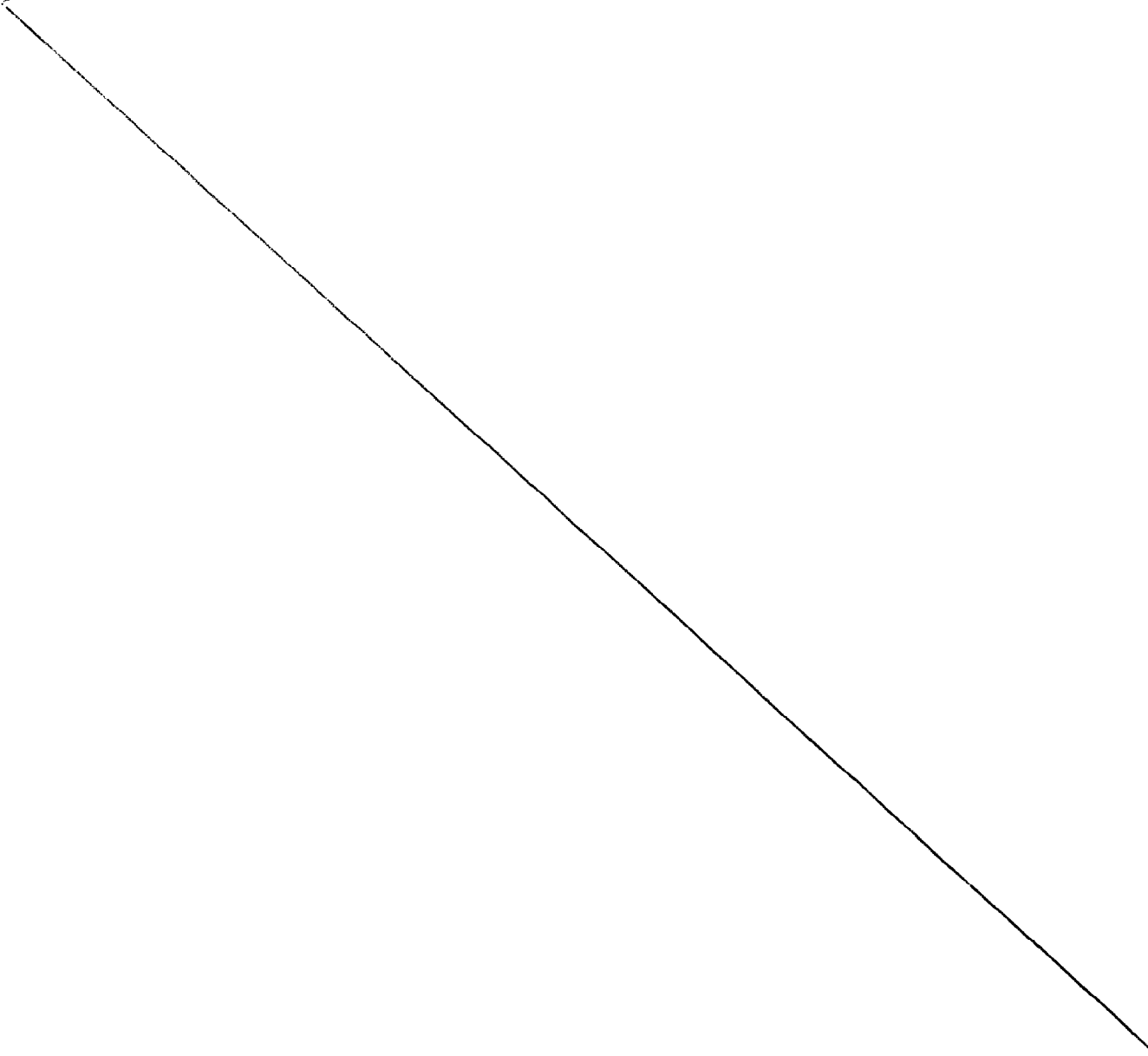
(2) A listing of ingredients consisting of calcium carbonate, the additive, and lactose and their proportions in the premix as prescribed under paragraph (d) of this section.

(3) Adequate directions for use to ensure a broiler chicken feed that is in compliance with the limitations prescribed in paragraph (d) of this section.

(4) An appropriate cautionary statement: "Caution: Store in a tightly-closed, light-resistant container in a cool, dry place."

(5) An expiration date of 1 year from the date of manufacture.

(6) A contact address and telephone number for reporting adverse reactions experienced by users, or to request a copy of the Material Safety Data Sheet for natamycin.



Dated: 3/24/04

cv03120

March 24, 2004.



Stephen F. Sundlof
Director,
Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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